

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

3-D MATRIX, INC., et al.,

Plaintiffs,

v.

MENICON CO. LTD., et al.,

Defendants.

*
*
*
*
*
*
*
*

Civil Action No. 14-cv-10205-IT

MEMORANDUM & ORDER

January 11, 2016

TALWANI, D.J.

I. Introduction

Plaintiffs 3-D Matrix, Inc., 3-D Matrix Ltd., and the Massachusetts Institute of Technology (“Plaintiffs”) bring this suit alleging that Defendants Menicon Co. Ltd. and B-Bridge International, Inc. (“Defendants”) infringe Plaintiffs’ patents, including United States Patent Nos. 5,670,483 (the “’483 Patent”) and 5,955,343 (the “’343 Patent”) (collectively, the “Patents-in-Suit”). The parties have asked the court to construe seven claim terms contained in the Patents-in-Suit. After reviewing the parties’ filings and holding a Markman hearing, the court issues the following claim construction.

II. Patents-in-Suit

This lawsuit involves two patents relating to the self-assembly of certain peptides into macroscopic membranes. See ’483 Patent, col. 1, ll. 34-35 (“This invention relates to the self-assembly of peptides into stable macroscopic membranes.”). According to the patentees, these membranes are “potentially useful in biomaterial applications such as slow-diffusion drug delivery systems, artificial skin, and separation matrices” ’343 Patent, Abstract. Plaintiffs

in this action allege that Defendants' product "PanaceaGel" infringes claims in the Patents-in-Suit. See Compl. [#1]. The Patents-in-Suit have similar specifications, and the '343 Patent is a "continuation-in-part of the '483 Patent." Pls.' Opening Claim Constr. Br. 2 [#42]. The '483 Patent was filed on November 30, 1994, and issued on September 23, 1997. The '343 Patent was filed on August 22, 1994, and issued on September 21, 1999.

III. Legal Framework

The construction of claim terms is a question of law. Markman v. Westview Instruments, 517 U.S. 370, 372 (1996) ("[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court."). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (citation omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of . . . the effective filing date of the patent application." Id. at 1313. In construing claim terms, courts look to "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. at 1314 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

A. The Language of the Claims

The claim construction analysis begins with the claims themselves. Id. at 1312. The claims of a patent "define the invention to which the patentee is entitled the right to exclude." Id. (quoting Innova, 381 F.3d at 1115). "[T]he context in which a term is used in the asserted claim may be highly instructive." Id. at 1314; see id. ("This court's cases provide numerous . . . examples in which the use of a term within the claim provides a firm basis for construing the

term.”). For example, “[b]ecause claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” Id. Additionally, “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” Id. at 1315.

B. The Specification

The claims “do not stand alone” but “are part of ‘a fully integrated written instrument,’ consisting principally of a specification” Id. at 1315 (internal citation omitted). “For this reason, claims ‘must be read in view of the specification, of which they are a part.’” Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (“Markman I”). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.’” Id. (quoting Vitronics Corp. v. Conceptor, Inc., 90 F.3d 1576, 1582 (1996)).

“[T]he specification may reveal a specific definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” Id. at 1316; see CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (stating that an inventor may “act as his own lexicographer” by “clearly set[ting] forth a definition of a disputed term in the specification”). “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of the claim scope by the inventor.” Phillips, 415 F.3d at 1316. Nevertheless, the court must be careful to “us[e] the specification [only] to interpret the meaning of a claim” and not to “import[] limitations from the specification into the claim.” Id. at 1323; see also id. (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against

confining the claims to those embodiments.”). Although this distinction “can be a difficult one to apply in practice[,] . . . the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.” Id.

C. The Patent Prosecution History

In construing claim terms, courts should also consider the patent’s prosecution history. Id. at 1317. The prosecution history consists of the record of the proceedings before the United States Patent and Trademark Office (“PTO”) and prior art cited during the examination of the patent. Id. “Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.” Id. The prosecution history can also provide evidence as to “whether the inventor limited the invention in the course of the prosecution, making the claim scope narrower than it would otherwise be.” Id. “Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” Id. As a result, courts must “not rely on the prosecution history to construe the meaning of the claim term to be narrower than it would otherwise be unless a patentee limited or surrendered claim scope through a clear and unmistakable disavowal.” 3M Innovative Props. Co. v. Tredegar Corp., 725 F.3d 1315, 1322 (Fed. Cir. 2013).

D. Extrinsic Evidence

Extrinsic evidence consists of “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” Phillips, 415 F.3d at 1317 (quoting Markman I, 52 F.3d at 980). “[W]hile extrinsic evidence can shed useful light on the relevant art, . . . it is less significant than the intrinsic record in determining the legally

operative meaning of the claim language.” Id. (internal quotation marks and citation omitted).

This is because extrinsic evidence suffers from a number of defects, including its independence from the patent, potential bias, and varying relevance. Id. at 1318-19. Such evidence is therefore “unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” Id. at 1319.

IV. Analysis

A. “Homogeneous”

The parties agree upon the definition of “homogeneous” as “of the same character structure, quality, etc.; essentially like; of the same nature.” See Joint Claim Constr. and Pre-Hr’g Statement [#48]. The court adopts the parties’ agreed-upon definition of this term.

B. “Amphiphilic Peptides”

The term “amphiphilic peptides” appears throughout the ’483 and ’343 Patents. Its use in Claim 1 of the ’483 Patent is typical:

1. A macroscopic membrane which is formed by the self-assembly of **amphiphilic peptides** in an aqueous solution containing monovalent metal cations, wherein the peptides contain 12 or more amino acids, have alternating hydrophobic and hydrophilic amino acids and are complementary and structurally compatible.

The parties’ proposed constructions of this term are as follows:

<u>Disputed Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
“amphiphilic peptides”	No construction necessary; the plain and ordinary meaning applies. Ordinary meaning: “peptides that contain hydrophobic and hydrophilic regions along their lengths”	“all of the amino acids of the peptides are either hydrophobic or hydrophilic, and the peptides have alternating hydrophobic and hydrophilic amino acids”

Plaintiffs contend that the ordinary meaning of the term “amphiphilic peptides” is

“peptides [that] contain hydrophobic and hydrophilic regions along their lengths,” and that the ordinary meaning of the term controls. See Pls.’ Responsive Claim Constr. Br. 2 [#46].

Defendants do not disagree with Plaintiffs’ articulation of the ordinary meaning of “amphiphilic peptides.” See Defs.’ Opening Claim Constr. Br. 4 [#43] (“At a fundamental level amphiphilic peptides contain hydrophobic and hydrophilic regions along their lengths.”); see also

Amphiphilic, ACADEMIC PRESS DICTIONARY OF SCI. & TECH. 100 (Academic Press, Inc. 1992), in Pls.’ Carnevale Decl. Ex. C [#44-3] (defining “amphiphilic” as “describing a substance containing both polar, water-soluble groups and non-polar, water-insoluble groups”). Rather, Defendants argue that the patentees in this case acted as their own lexicographers and redefined the term “amphiphilic peptides,” and that the patentees’ lexicography governs.

“The plain meaning of claim language ordinarily controls.” InterDigital Commc’ns, LLC v. Int’l Trade Cmm’n, 690 F.3d 1318, 1324 (Fed. Cir. 2012). There are two exceptions to this general rule: “1) when a patentee sets out a definition and acts as [its] own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1330 (Fed. Cir. 2012) (quoting Thorner v. Sony Comput. Entm’t Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). “To act as its own lexicographer, . . . ‘the patentee must clearly express an intent’ to redefine the term.” Id. (quoting Thorner, 669 F.3d at 1365). Thus, the question presented is whether the language of the claim language, specification, and prosecution history reflect a clear intent on the part of the patentees in this case to redefine the term “amphiphilic peptides” as something other than its ordinary meaning. The court finds no such clear intent here.

First, the language of the claims is more consistent with the ordinary meaning of “amphiphilic peptides” than with Defendants’ proposed construction. Defendants’ proposed

construction of “amphiphilic peptides” as peptides having “alternating hydrophobic and hydrophilic amino acids” would render claim language redundant and the term “amphiphilic” superfluous. See ’483 Patent, Claim 1 (“A macroscopic membrane formed by the self-assembly of *amphiphilic peptides* . . . wherein the peptides . . . *have alternating hydrophilic and hydrophobic amino acids*” (emphasis added)); see also Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 781 (Fed. Cir. 2010) (“[Courts] construe claims with an eye toward giving effect to their terms.”); Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); Deere & Co. v. Bush Hog, LLC, 703 F.3d 1349, 1354 (Fed. Cir. 2012) (construing claim term in a manner so as to “not render the term superfluous”).

Second, the prosecution history reflects that the patentees originally described Claim 1 as “[a] macroscopic membrane which is formed by self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations.” Pls.’ Supp. Decl. Carnevale Ex. C at 2 [#47-3]. The prosecution history further reflects that the patentees, in response to a PTO office action, later added the phrase “wherein the peptides have alternating hydrophobic and hydrophilic amino acids.” Id. The patentees’ later insertion of the requirement for “alternating hydrophobic and hydrophilic amino acids” suggests that the patentees did not understand the term “amphiphilic peptides” to include such a requirement.

Finally, the specifications do not demonstrate a clear intent on the part of the patentee to redefine “amphiphilic peptides.” Defendants point to language in the specifications stating: “Peptides which form membranes are characterized as being amphiphilic, **i.e.** having alternating hydrophobic and hydrophilic amino acid residues” ’483 Patent, col. 1, ll. 36-41 (emphasis added). However, the use of “i.e.” does not invariably indicate that the patentee intended to act

as its own lexicographer. Rather, whether the patentee used the term “i.e.” in a definitional sense must be determined in context. See Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1370 (Fed. Cir. 2012) (concluding that patentee’s use of phrase “each side of the disc—i.e., each recording plane,” when read in context, was not definitional); Pfizer, Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364, 1373-74 (Fed. Cir. 2005) (holding that patentee’s reference to “saccharides (i.e., sugars)” was not definitional in view of other patent language and extrinsic evidence as to the ordinary meaning of “saccharides”). Significantly, the ’343 specification also includes the language: “Peptides which form membranes are characterized as being amphiphilic, **e.g.**, having alternating hydrophobic and hydrophilic amino acid residues” ’343 Patent, col. 1, ll. 49-51 (emphasis added). The specifications’ interchangeable use of “i.e” and “e.g.” creates ambiguity as to whether the patentee intended to redefine the term “amphiphilic peptides” to require alternating hydrophobic and hydrophilic amino acids, or intended to use peptides with alternating hydrophobic and hydrophilic amino acids as an example of “amphiphilic peptides.”

Absent a clear expression of intent on the part of the patentee to redefine the term “amphiphilic peptides,” the court construes the term in accordance with its ordinary meaning as “peptides that contain hydrophobic and hydrophilic regions along their lengths.”

C. “Complementary” and “Structurally Compatible”

The terms “complementary” and “structurally compatible” appear in numerous claims in the ’483 and ’343 Patents. Their use in Claims 1 and 37 of the ’483 Patent is typical:

1. A macroscopic membrane which is formed by the self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the peptides contain 12 or more amino acids, have alternating hydrophobic and hydrophilic amino acids and are **complementary** and **structurally compatible**.
37. A method for forming a macroscopic membrane comprising forming an aqueous mixture of peptides, which are 12 or more amino acids in length, have alternating nonpolar and hydrophilic amino acids, and are **complementary** and **structurally**

compatible, and monovalent metal cations under conditions suitable for self-assembly of the peptide into the macroscopic membrane and allowing the membrane to be formed.

The parties' proposed constructions of these terms are as follows:

<u>Disputed Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
"complementary"	"the ability of peptides to interact through ionized pairs or hydrogen bonds"	"the peptides form ionized pairs between each of the hydrophilic side chains"
"structurally compatible"	"the ability of complementary peptides to maintain a constant distance between their peptide backbones"	"the peptides maintain a constant distance between their peptide backbones"

Plaintiffs argue that the patentees acted as their own lexicographers by clearly setting forth definitions of the terms "complementary" and "structurally compatible" in the specifications, and that the patentees' lexicography controls. Accordingly, Plaintiffs propose constructions of the terms "complementary" and "structurally compatible" that track the patentees' definitions in the specifications. See '483 Patent, col. 1, ll. 40-44 ("Complementary refers to the ability of the peptides to interact through ionized pairs and/or hydrogen bonds which form between their hydrophilic side-chains."); '483 Patent, col. 1, ll. 43-46 ("[S]tructurally compatible refers to the ability of complementary peptides to maintain a constant distance between their peptide backbones."); '483 Patent, col. 5, ll. 12-16 ("An additional stabilizing factor is that complementary peptides maintain a constant distance between the peptide backbones. Peptides which can maintain a constant distance upon pairing are referred to herein as structurally compatible.").

Defendants agree that the patentees acted as their own lexicographers and set forth definitions of these terms. See Defs.' Reply Claim Constr. Br. 11 [#45] ("Both sides agree that

the patentee provided a definition of the term ‘complementary’ in all of the asserted claims.”); id. at 13 (“[T]he parties agree that the patentees acted as their own lexicographers.”). Nevertheless, Defendants urge the court to reject the patentees’ lexicography. In doing so, Defendants argue that the claims require that the peptides *actually* bond and maintain a constant distance between their peptide backbones, not merely that the peptides have the *ability* to do so.

The court finds clear intent on the part of the patentees in this instance to act as their own lexicographers and redefine the terms “complementary” and “structurally compatible.” The specifications expressly set forth definitions of these terms. Moreover, the language of the claims is consistent with the patentees’ lexicography and inconsistent with Defendants’ proposed construction. The language of Claim 37 of the ’483 Patent suggests that the terms “complementary” and “structurally compatible” describe characteristics of the peptides *before* the peptides interact and form membranes. See ’483 Patent, Claim 37 (describing a “method for forming a macroscopic membrane comprising forming an aqueous mixture of peptides, which are . . . complementary and structurally compatible . . . and allowing the membrane to be formed”). Consistent with this claim language, the patentees defined “complementary” and “structurally compatible” as characteristics of the peptides whether or not the peptides have yet interacted, bonded, and formed a membrane. See ’483 Patent, col. 1, ll. 40-44 (“Complementary refers to the *ability* of the peptides to interact through ionized pairs and/or hydrogen bonds which form between their hydrophilic side-chains.” (emphasis added)); ’483 Patent, col. 1, ll. 43-46 (“Structurally compatible refers to the *ability* of complementary peptides to maintain a constant distance between their peptide backbones.” (emphasis added)). In contrast, Defendants’ proposed constructions of “complementary” and “structurally compatible,” as applied to method Claim 37, would require an impossibility—that the peptides actually form pairs and maintain a

constant distance between their backbones before the peptides interact and form a membrane.

Finally, the prosecution history suggests that the PTO Examiner adopted the patentees' definitions during examination of the patent. See Defs.' Ex. C, 3DM 000705-06 [#43-4] ("The specification shows that peptides capable of forming macroscopic membranes must . . . be 'complementary,' defined by Applicants as capable of ion-pair or hydrogen bonding interactions between side chains . . . [and] be 'structurally compatible,' defined by Applicants as capable of maintaining a constant distance between peptide backbones . . .").

Defendants urge the court to reject the patentees' lexicography on the ground that the claims are "product-by-process" claims that require that the peptides actually bond and maintain a constant distance between their peptide backbones, not merely that the peptides have the ability to do so. "A product-by-process claim is 'one in which the product is defined at least in part in terms of the method or process by which it is made.'" SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1315 (Fed. Cir. 2006) (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158 (1989)). "[P]rocess terms that define the product in a product-by-process claim serve as enforceable limitations." Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1291 (Fed. Cir. 2009); see id. at 1295 (construing "obtainable by" as a process term with the meaning "obtained by" in a product-by-process claim).

Even if the court were to construe the claims at issue as a product-by-process claims, the terms "complementary" and "structurally compatible" are not process terms. "Complementary" and "structurally compatible" do not describe steps or acts in a manufacturing process, but rather describe characteristics of the peptides used in the asserted process. See 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371-73 (Fed. Cir. 2003) (holding that "superimposed" was not a process term but instead "describes a structural relationship between

the embossed patterns”); Hazani v. United States Int’l Trade Comm’n, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (concluding that “chemically engraved” was not a process term); Vanguard Prods. Co. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed. Cir. 2000) (construing the term “integral” to describe a structural relationship rather than a manufacturing process); see also 3M Innovative Properties Co., 350 F.3d at 1371 (“[E]ven words of limitation that can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense . . .”).

The court sees no basis for departing from the patentees’ lexicography. Accordingly, the court adopts Plaintiffs’ proposed construction of “complementary” as “the ability of peptides to interact through ionized pairs or hydrogen bonds,” and adopts Plaintiffs’ proposed construction of “structurally compatible” as “the ability of complementary peptides to maintain a constant distance between their peptide backbones.”

D. “macroscopic membrane”

The term “macroscopic membrane” appears throughout the ’483 and ’343 Patents. Its use in Claim 1 of the ’483 Patent and Claim 1 of the ’343 Patent is typical:

1. A **macroscopic membrane** which is formed by the self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the peptides contain 12 or more amino acids, have alternating hydrophobic and hydrophilic amino acids and are complementary and structurally compatible.

’483 Patent, Claim 1.

1. A method for in vitro cell culture comprising:
 - a) adding a **macroscopic membrane** which is formed by the self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the peptides are 12 or more amino acids . . . , to a cell culture medium comprising cells, thereby forming a membrane/culture mixture

’343 Patent, Claim 1.

The parties’ proposed constructions of this term are as follows:

<u>Disputed Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
"macroscopic membrane"	<p>No construction necessary. The preamble is not a limitation on the claims.</p> <p>Alternatively, "a macroscopic material of interwoven filaments."</p>	"A thin sheet or layer."

Plaintiffs assert that the term "macroscopic membrane" is not a claim limitation because it appears in the preamble of the claims, and therefore no construction is necessary. Defendants disagree, arguing that "macroscopic membrane" is a claim limitation that requires construction.

"Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Corning Glass Works v. Sumitomo Electric USA, Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)). In general, "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" Id. (quoting Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997)). Conversely, "a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Id. (quoting Pitney Bowes Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)). "Moreover, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Id. Compare Kropa v. Robie, 187 F.2d 150, 152 (Fed. Cir. 1951) (holding that preamble term "abrasive article" was "essential to point out the invention defined by the counts"), with Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672

F.3d 1335, 1347 (Fed. Cir. 2012) (concluding that preamble did not limit the claims where “nothing in the prosecution history suggest[ed] that the preamble language was considered necessary to the patentability of the claims”).

The term “macroscopic membrane” appears in the preamble of Claim 1 of the ’483 Patent and the body of Claim 1 of the ’343 Patent. Thus, at least as to the ’343 Patent, “macroscopic membrane” is a claim limitation. Moreover, the court agrees with Defendants that “macroscopic membrane” is a claim limitation as to the ’483 Patent as well. Although the term appears in the preamble of Claim 1 of the ’483 Patent, the patentees relied on the formation of a “macroscopic membrane” to distinguish the invention from prior art. See Defs.’ Ex. C, 3DM 000628 [#43-6] (“The most important distinction between the claimed invention and [Osterman et al.’s] oligopeptide is that they did not observe macroscopic membrane formation although they noted microscopic aggregation.”); id. at 3DM 000629 [#43-7] (“Gay et al. teach that a leucine rich peptide produced by the Drosophila Toll gene will aggregate to form a gel, which is water soluble. Gay et al. do not teach that any peptide capable of forming a β -sheet could be employed to produce a stable macroscopic membrane, such as those claimed herein.”); id. at 3DM 000631 [#43-7]; see also ’483 Patent, col. 1, ll. 25-36 (“At present, the self-assembly of peptides into macroscopic membranes has not been reported. . . . This invention relates to the self-assembly of peptides into stable macroscopic membranes.”). Thus, the court concludes that “macroscopic membrane” is a claim limitation for both patents.

Turning to the meaning of “macroscopic membrane,” the parties agree that “macroscopic” should be given its plain and ordinary meaning, and further agree as to what that plain and ordinary meaning is. See Defs.’ Opening Claim Constr. Br. 12 [#43]; see also Pls.’ Supp. Br. on Claim Constr. 7 [#55]. Accordingly, the court concludes that it need not construe

the term “macroscopic,” and that the plain and ordinary meaning of the term applies.

The parties’ dispute centers on the term “membrane.” Plaintiffs argue that, if the court concludes that “membrane” is a claim limitation, then the court need not issue a claim construction because the plain and ordinary meaning of the term applies. Alternatively, Plaintiffs argue that, if the court decides to construe “membrane,” then the court should construe it to mean a “material of interwoven filaments.” Defendants assert that the court’s construction of the term “membrane” is required in order to resolve a dispute between the parties. Defendants further assert that “membrane” should be defined as “a thin sheet or layer.”

A court may construe a claim term to have its plain and ordinary meaning when such a construction resolves a dispute between the parties. See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1361 (Fed. Cir. 2008). However, “[a] determination that a claim term ‘needs no construction’ or has the ‘plain and ordinary meaning’ may be inadequate when a term has more than one ‘ordinary’ meaning or when reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.” Id.; see also id. at 1360 (“When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.”). Here, the parties raise an actual dispute as to the scope of the claim language. Accordingly, the court finds that construction of the term “membrane” is necessary.

“Membrane” is a term that has a plain and ordinary meaning that is widely understood. See, e.g., Defs.’ Ex. E [#43-11], *Membrane*, GRANT & HACKH’S CHEMICAL DICTIONARY (5th ed. 1987) (defining “membrane” as a “thin, enveloping or lining substance which divides a space or an organ; . . . [a] tissue that permits the passage of certain substances, *e.g.*, ions, but prevents the passage of others, *e.g.*, colloids”); Defs.’ Ex. F [#43-12], *Membrane*, AMERICAN HERITAGE DICTIONARY (2d College ed. 1985) (defining “membrane” as “1. *Biol.* A thin, pliable layer of

tissue covering surfaces or separating or connecting regions of structures, or organs of an animal or plant. . . . 3. *Chem.* A thin sheet of natural or synthetic material that is permeable to substances in solution.”); Defs.’ Ex. G [#43-13], Kirk-Othmer, *ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY* vol. 16, p. 137 (4th ed. 1995) (“[A] membrane is a discrete, thin interface that moderates the permeation of chemical species in contact with it.”). Defendants’ proposed construction is in line with the plain and ordinary meaning of the term.

Based on the above, the ordinary meaning of “membrane” includes “a thin soft pliable sheet or layer especially of animal or plant origin” and “a discrete, thin interface that moderates permeation.” From these definitions, the court drops the phrases “soft pliable” and “especially of animal or plant origin” because these phrases have no apparent relevance to this case and find no support in the claims, specifications, or prosecution history. The court finds the remainder of the ordinary meaning of “membrane” to be consistent with the specifications. See ’343 Patent, col. 2, ll. 17-21 (“The membranes are thin, transparent and resemble high density felt under high magnification. . . . They . . . are permeable”); ’343 Patent, col. 3, l. 46 – col. 4, l. 2 (“The EAK16 peptide was observed to form a membranous structure with the appearance of a piece of transparent, thin . . . plastic membrane At low magnifications (50-100x), the structure looks like a flat membrane. . . . The architecture of the structure appears to resemble high density felt or cloth.”); ’343 Patent, col. 10, l. 66 – col. 11, l. 1 (“[The membranes] can be used in numerous applications in which permeable and water insoluble material are appropriate”); ’483 Patent, col. 2, ll. 11-15 (“[T]he macroscopic membranes provided by this invention are potentially useful as biomaterial for medical products, as vehicles for slow-diffusion drug delivery, as separation matrices, and for other uses requiring permeable and water-insoluble material.”); ’483 Patent, col. 7, ll. 49-52 (“The membranes can be transferred from one solution to another using a solid

support such as a spatula. They can be broken by cutting, tearing or shearing.”).

Plaintiffs’ proposed construction appears to broaden the term “membrane” beyond its plain and ordinary meaning to include all materials possessing interwoven filaments. Plaintiffs’ proposed broadening of the term, however, is not supported by the claim language, specification, or prosecution history. Starting with the language of the claims, the court finds it significant that, although the patentees used the terms “material” and “structure” at various points in the specifications, the patentees chose to use the term “membrane” instead of “material” or “structure” in the claims. See Medisim Ltd. v. BestMed LLC, No. 10 Civ. 2463, 2011 WL 2693896, at *6 (S.D.N.Y. July 8, 2011) (“I find it significant that the patent uses the word ‘membrane’ and therefore decline to substitute the word ‘material’ for ‘membrane.’”); Regents of the Univ. of MN v. AGA Med. Corp., 660 F. Supp. 2d 1037, 1054 (D. Minn. 2009) (“[T]he court construes the term ‘membrane’ . . . to mean ‘a thin sheet or layer of material’ . . . rather than simply ‘material’ . . .”).

Turning to the specifications, Plaintiffs’ argument that “membrane” should be defined as a “material of interwoven filaments” is based on an excerpt from the ’483 specification. See ’483 Patent, col. 3, ll. 25-48 (“The EAK16 peptide was observed to form a membranous structure with the appearance of a piece of transparent, thin (about 10-20 μ m) plastic membrane . . . [A scanning electron microscope] revealed that the membrane is made up of individual filaments that are interwoven.”). This passage is an excerpt from the specification discussing the appearance of a preferred embodiment (EAK 16) when viewed through a microscope at a certain magnification. There is no indication that the patentees intended this passage to redefine the ordinary meaning of the term “membrane.” Nor does the passage suggest that the patentees intended to claim all materials possessing interwoven filaments.

Finally, Plaintiffs’ proposed construction is in tension with the prosecution history. To overcome an objection from the PTO, the patentees distinguished their claimed invention from prior art involving materials that similarly could possess interwoven filaments but did not form membranes. See Defs.’ Ex. C, 3DM 000628 [#43-6] (“The most important distinction between the claimed invention and [Osterman et al.’s] oligopeptide is that they did not observe macroscopic membrane formation although they noted microscopic aggregation.”); id. at 3DM 000629 [#43-7] (“Gay et al. teach that a leucine rich peptide produced by the Drosophila Toll gene will aggregate to form a gel, which is water soluble. Gay et al. do not teach that any peptide capable of forming a β -sheet could be employed to produce a stable macroscopic membrane, such as those claimed herein.”); id. at 3DM 000630 (“The references further do not teach membranes possessing the stability properties of the claimed membranes.”). The patentees’ attempt to distinguish the claimed invention from these other materials suggests that “membrane” likely requires something more than interwoven filaments.

The court is not persuaded that Plaintiffs’ broader construction is appropriate. See Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003) (“In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meaning attributed to them by those of ordinary skill in the art.”). The court therefore construes “membrane” in accordance with its plain and ordinary meaning as “a thin sheet or layer that moderates permeation.”

E. “alternating hydrophobic and hydrophilic amino acids”

The term “alternating hydrophobic and hydrophilic amino acids” appears throughout the ’483 and ’343 Patents. Its use in Claim 1 of the ’483 Patent is typical:

1. A macroscopic membrane which is formed by the self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the

peptides contain 12 or more amino acids, have **alternating hydrophobic and hydrophilic amino acids** and are complementary and structurally compatible.

The parties' proposed constructions of this term are as follows:

<u>Disputed Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
"alternating hydrophobic and hydrophilic amino acids"	No construction necessary; the plain and ordinary meaning should apply.	"all the hydrophobic and hydrophilic amino acids are completely alternating, i.e. no adjacent amino acids are both hydrophobic or hydrophilic"

Plaintiffs contend that the term "alternating hydrophobic and hydrophilic amino acids" needs no construction because the ordinary meaning of the term applies. Although Plaintiffs do not explain what the ordinary meaning is, Plaintiffs would include mismatches, *i.e.* non-alternating amino acids. In contrast, Defendants argue that the patentees disavowed mismatches during prosecution in order to overcome PTO enablement and prior-art objections. According to Defendants, the prosecution history demonstrates that both the patentees and the PTO examiner understood the limitation of "alternating hydrophobic and hydrophilic amino acids" to require a completely alternating sequence.

The parties' dispute boils down to whether the term "alternating hydrophobic and hydrophilic amino acids" permits exceptions/mismatches, or whether the term requires a completely alternating sequence. Because the parties dispute the scope of the claim term, the court finds that construction of the term is necessary in order to resolve the dispute. See O2 Micro Int'l Ltd., 521 F.3d at 1361 ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." Id.; see also id. at 1360-61 (holding that the district court erred in failing to construe

“only if” where the parties disputed whether the term allowed for exceptions).

Turning to the meaning of the term, Plaintiffs argue that the specification contains language addressing mismatches, and that this language demonstrates that the patentees intended the term “alternating” to include peptides with mismatches. In particular, Plaintiffs point to the following passage:

Peptides, which are not perfectly complementary or structurally compatible, can be thought of as containing mismatches analogous to mismatched base pairs in the hybridization of nucleic acids. Peptides containing mismatches can form membranes if the disruptive force of the mismatched pair is dominated by the overall stability of the interpeptide interaction. Functionally, such peptides can also be considered as complementary and structurally compatible. For example, a mismatched amino acid pair may be tolerated if it is surrounded by several perfectly matched pairs on each side. Mismatched peptides can be tested for ability to self-assemble into macroscopic membranes using the methods described herein.

’483 Patent, col. 6, ll. 12-24. This passage, however, relates to peptides that are not perfectly complementary and structurally compatible, not to peptides that have mismatches in their alternating amino acid sequence. Moreover, even if this passage could be read to relate to peptides with mismatches in their alternating sequence, the court agrees with Defendants that the patentees surrendered such mismatches at two points during the prosecution history.

“The prosecution history constitutes a public record of the patentee’s representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention.” Seachange Int’l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1372 (Fed. Cir. 2005). “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of the prosecution, making the claim scope narrower than it would otherwise be.”

Phillips, 415 F.3d at 1317. “Thus, in construing the claim, [the court] consider[s] the prosecution

history to determine whether the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms” through, for instance, “amendments to claims” or “arguments to overcome and distinguish references.” Seachange Int’l, Inc., 413 F.3d at 1372 (internal quotation marks and citations omitted).

First, the court finds that, although the patentees initially sought to include peptides with mismatches in the patent, the patentees amended their claims and surrendered this goal in order to overcome a PTO enablement objection. The patentees originally proposed Claim 1 as “A macroscopic membrane which is formed by self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations.” Defs.’ Ex. C, 3DM000255 [#43-4]. Although the specifications described the preferred embodiments as having alternating hydrophobic and hydrophilic amino acids, the claim language did not include the limitation that the amino acids alternate. Additionally, the specifications included the above passage regarding mismatches.

The PTO rejected the patentees’ application based on enablement, stating: “the specification states that peptides that do not meet the criteria required by Applicants’ model may also form membranes. The specification does not, however, provide guidance regarding how much deviation from the model would be expected to be tolerated before interfering with membrane formation.” Defs.’ Ex. C, 3DM000660 [#43-7]; see also id. at 3DM000608 [#43-6] (“[T]he specification provides inadequate guidance to enable the skilled artisan to make and use the claimed invention with peptides comprising any combination of hydrophobic and hydrophilic amino acids. . . . Undue experimentation would be required of the skilled artisan to determine which of the myriad possible peptides encompassed by the instant claims would form macroscopic membranes” (emphasis in original)).

In response to the PTO enablement objection, the patentees argued to the PTO that “with

rational experimentation design, the worker of skill in the art is enabled to design peptides which deviate from the model and will form macroscopic membranes employing the teachings of the specification as guidance.” Defs.’ Ex. C, 3DM000706 [#43-8]. The PTO again rejected the patentees’ application on enablement grounds, and responded to the patentees by stating:

This argument is not deemed to be persuasive. Applicants have not pointed to specific guidance in the specification which would enable a person of ordinary skill in the art to practice the full scope of the claimed invention (i.e., to form macroscopic membranes from peptides which do not meet the criteria disclosed by the specification as essential to such membrane formation) without undue experimentation.

Defs.’ Ex. C, 3DM000706 [#43-8].

In response to this rejection, the patentees decided to amend their claims to require “alternating hydrophobic and hydrophilic amino acids,” instead of continuing to argue that the claims should include mismatches (*i.e.* deviations from the model). Defs.’ Ex. C, 3DM000748-50 [#43-8]. The PTO dropped its enablement objection and approved the patent with the added limitations. The patentees’ decision to add the limitation that the peptides have “alternating hydrophobic and hydrophilic amino acids” to overcome the PTO’s objection that the patent did not “provide guidance regarding how much deviation from the model would be expected to be tolerated,” suggests that the patentees did not understand “alternating” to include deviations and mismatches. Based on this prosecution history, the court is persuaded that the patentees surrendered deviation/mismatches, and accordingly added the requirement for alternation, in order to overcome the enablement objection.

Second, the court finds that the patentees disclaimed irregular sequences during the prosecution in order to overcome a PTO prior-art objection. The prosecution history reflects that the PTO initially rejected the patentees’ claims as obvious over prior art including Gay et al., whose peptides contain a sequence of ten alternating amino acids followed by a few non-

alternating and alternating pairs. See Defs.’ Ex. C, 3DM000610-11 [#43-6]; see also Markman Tr. 74-75 [#53] (describing the Gay et al. peptide). In response to this objection, the patentees argued to the PTO that their claimed peptides were distinguishable from Gay et al.’s peptides on the ground that Gay et al.’s peptides “have irregular sequences.” See Defs.’ Ex. C, 3DM000630 [#43-7]. The patentees clarified that, in contrast to Gay et al.’s peptides, “[t]he claimed membranes possess alternating hydrophilic and hydrophobic residues.” Id. The patentees’ act of distinguishing their claimed “alternating” sequences from Gay et al.’s “irregular sequences” served to narrow the scope of the patentees’ claims to regular sequences. See Seachange Int’l Inc., 413 F.3d at 1373 (“[W]here an applicant argues that a claim possesses a feature that prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of the otherwise broad claim language.”); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) (“[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection.”).¹ Thus, to the extent that “alternating” could be understood to include mismatches or irregular sequences, the patentees surrendered such meaning.

The court also notes that in Plaintiffs’ opening and reply briefs, Plaintiffs made no attempt to set forth a definition of “alternating” or to otherwise quantify how many mismatches a peptide could possess and still be considered “alternating.” In response to the court’s concern, Plaintiffs set forth a definition of “alternating hydrophobic and hydrophilic amino acids” in their post-hearing brief as: “hydrophobic amino acid residues adjacent to hydrophilic amino acid

¹ While the patentees argued before the PTO that the Gay et al. peptides were not “alternating” but instead had “irregular sequences,” Plaintiffs now set forth an understanding of “alternating” that Plaintiffs admit would include the Gay et al. peptides. See Markman Tr. 82-83 [#53].

residues with sufficient regularity to support stable β -sheet formation.” Pls.’ Supp. Br. 3 [#55].

In other words, Plaintiffs attempt to define the term as, and thus claim, any sequence that forms a membrane, or “whatever works.” This, however, was the argument rejected by the PTO on enablement grounds and that resulted in the patentees amending their claims to require alternation.

For the above reasons, the court adopts the definition of “alternating hydrophobic and hydrophilic amino acids” as “completely alternating hydrophobic and hydrophilic amino acids, i.e. no adjacent amino acids are both hydrophobic or both hydrophilic.”

F. “under conditions suitable for self-assembly of the peptide into the macroscopic membrane”

The term “under conditions suitable for self-assembly of the peptide into the macroscopic membrane” appears in Claim 37 of the ’483 Patent:

37. A method for forming a macroscopic membrane comprising forming an aqueous mixture of peptides, which are 12 or more amino acids in length, have alternating nonpolar and hydrophilic amino acids, and are complementary and structurally compatible, and monovalent metal cations **under conditions suitable for self-assembly of the peptide into the macroscopic membrane** and allowing the membrane to be formed.

The parties’ proposed constructions of this term are as follows:

<u>Disputed Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
“under conditions suitable for self-assembly of the peptide into the macroscopic membrane”	No construction necessary; the plain and ordinary meaning applies.	Indefinite

Defendants argue that “if any of the above terms [in subsections A through E] are construed as proposed by [Plaintiffs], the ‘conditions suitable’ limitation is indefinite.” Defs.’ Opening Claim Constr. Br. 25 [#43]. Defendants elaborate that “if the above disputed terms are

construed broader than the construction proposed by Defendants[,] one of ordinary skill in the art would be unable to know the true limits of the ‘various’ conditions suitable” Id. at 23.

Defendants’ argument appears to conflate the “conditions suitable” term with other claim limitations, suggesting that that the “conditions suitable for self-assembly” are that the peptides have alternating hydrophobic and hydrophilic amino acids and are complementary, structurally compatible, and amphiphilic. Defendants’ argument, however, renders claim language redundant and the “conditions suitable” term superfluous. “[Courts] construe claims with an eye toward giving effect to their terms.” Haemonetics Corp., 607 F.3d at 781; see also Merck & Co., 395 F.3d at 1372 (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”). The court therefore is not persuaded by Defendants’ argument that the “conditions suitable” term encompasses the other claim limitations.

Nevertheless, the question remains as to the meaning of the “conditions suitable” term, as well as whether such term is indefinite. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Nautilus, Inc. v. Biosig Instruments, Inc., 134 S.Ct. 2120, 2124 (2014). “[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.” Id. at 2129 (quoting Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916)).

Plaintiffs argue that the language of the claims and the specifications provide sufficient guidance to inform a person skilled in the art about the scope of the claims. See, e.g., ’483 Patent, Claim 45 (“suitable conditions comprise the absence of an inhibitor”); ’483 Patent, Claim 48 (“suitable conditions comprise a pH of less than 12”); ’483 Patent, col. 6, ll. 54-57 (“Macroscopic membranes . . . appear after addition of sodium phosphate to a water-peptide

solution to an approximate final concentration of 100 mg/ml.”); ’483 Patent, col. 7, ll. 14-16 (“Concentrations of monovalent metal cations (NaCl) as low as 5 mM and as high as 5M have been found to induce membrane formation within a few minutes.”); see also Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1373 (Fed. Cir. 2014) (“We recognize that a patent which defines a claim phrase through examples may satisfy the definiteness requirement.”).

The issues of indefiniteness and claim constructions are often “intimately related.” See Manzo, Claim Construction in the Federal Circuit § 4.1 (2012 ed.); see also Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (“[T]he same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction.”). There are, however, some distinctions between claim construction and indefiniteness. For instance, unlike claim construction, indefiniteness is a defense that the allegedly infringing party must prove by “clear and convincing” evidence. Microsoft Corp. v. i4i Ltd. P’ship, 131 S.Ct. 2238, 2242 (2011). Moreover, “unlike a Markman proceeding that gives meaning to patent claims, indefiniteness invalidates the claims entirely.” CSB-Sys. Int’l Inc. v. SAP Am., Inc., No. 10-2156, 2011 WL 3240838, at *18 (E.D. Pa. July 28, 2011). Accordingly, courts have recognized that there are “reasons to defer ruling on indefiniteness until the summary judgment stage.” Koninklijke Philips Elecs. v. Zoll Med. Corp., 914 F. Supp. 2d 89, 100 (D. Mass. 2012). This is especially so if “the claim language itself is amenable to construction but is alleged to be indefinite as applied.” Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 887 F. Supp. 2d 303, 313 (D. Mass. 2012); see also Takeda Pharm. Co. v. Handa Pharms., LLC, 2012 WL 1243109, at *16 (N.D. Cal. April 11, 2012) (deferring indefiniteness until summary judgment because whether a person skilled in the art could determine relevant amounts without undue experimentation was a “largely factual” inquiry).

Here, Defendants offer no argument apart from their argument discussed above conflating the “conditions suitable” term with the other claim limitations. The court thus concludes that the briefing and record are not sufficiently developed at this stage to decide the question of indefiniteness. See Momenta Pharm., Inc., 887 F. Supp. 2d at 313 (“[Indefiniteness] needs to be resolved, and will be, at a later point upon a complete record.”); Waddington N. Am., Inc. v. Sabert Corp., No. 09-4883, 2010 WL 4363137, at *3 (D.N.J. Oct. 27, 2010) (“[P]ractical considerations . . . militate against determining indefiniteness prior to the end of fact or expert discovery.”). Moreover, from what the court can glean from Defendants’ filing, Defendants’ indefiniteness challenge does not center on the meaning of the words in the “conditions suitable” term. See Cipher Pharm. Inc. v. Actavis Labs. FL, Inc., 99 F. Supp. 3d 508, 514 (D.N.J. 2015) (deferring ruling on indefiniteness where defendants’ indefiniteness argument “[did] not directly implicate the construction of the word ‘about’” and “venture[d] far beyond the inherent meaning of the words”). The court therefore declines to rule on indefiniteness at this stage.

V. Conclusion

For the foregoing reasons, the claim terms are construed as follows:

1. The term “homogeneous” means “of the same character structure, quality, etc.; essentially like; of the same nature.”
2. The term “amphiphilic peptides,” means “peptides that contain hydrophobic and hydrophilic regions along their lengths.”
3. The term “complementary” means “the ability of peptides to interact through ionized pairs or hydrogen bonds.”
4. The term “structurally compatible” means “the ability of complementary peptides to maintain a constant distance between their peptide backbones.”

5. The term “membrane” means “a thin sheet or layer that moderates permeation.”
6. The term “alternating hydrophobic and hydrophilic amino acids” means “completely alternating hydrophobic and hydrophilic amino acids, i.e. no adjacent amino acids are both hydrophobic or both hydrophilic.”

IT IS SO ORDERED.

Date: January 11, 2016

/s/ Indira Talwani
United States District Judge